K031073

NOV - 5 2003

510(k) Summary

04/03/03

PerioGlas® Plus – Settable Bone Graft Substitute

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	1 Progress Boulevard, #33 Alachua, FL 32615
Telephone:	(386) 462-7660
Facsimile:	(386) 418-1465
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	PerioGlas Plus – Settable Bone Graft Substitute
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Classification Name:	Unknown

3. Legally Marketed Predicate Device:

Predicate #1:	PerioGlas – Synthetic Bone Graft Particulate [K992416, K962492, K930115]
Predicate #2:	CAPSET Calcium Sulfate Bone Graft Plaster [K955096]

4. Device Description

PerioGlas Plus is a synthetic resorbable osteoconductive bone graft substitute composed of a calcium phospho-silicate material and a calcium sulfate binder. The device is intended for dental intraosseous, oral, and maxillofacial bony defects. The inorganic calcium and phosphorous components are thermally incorporated in a sodium silicate network (PerioGlas) designed specifically for its absorbability and osteoconductive nature. The calcium sulfate component binds the PerioGlas particles together at the time of implantation and is absorbed from the graft site over the first several weeks following implantation. On absorption of the calcium sulfate, the PerioGlas particles remain in the graft site and are progressively aborbed and replaced by host bone during the healing process.

5. Intended Use

PerioGlas Plus – Settable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. PerioGlas Plus is indicated to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral and maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy,

osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); craniofacial augmentation; sinus lifts; cystic defects. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

6. Technological Characteristics

The technological characteristics of PerioGlas Plus, PerioGlas, and CAPSET are similar, although not identical. All three devices are designed to be osteoconductive space-filling materials to be packed into or over osseous defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. To meet this design, PerioGlas Plus and the predicate devices are similar in nature; all three devices are synthetic, inorganic, biocompatible and osteoconductive materials.

The main technological characteristic difference between PerioGlas Plus and the predicate devices is their composition. PerioGlas is composed of particulate Bioglass® (see description). CAPSET is composed of powdered calcium sulfate hemihydrate which, when combined with an aqueous-based setting solution, is chemically converted to calcium sulfate dihydrate. PerioGlas Plus is composed of particulate Bioglass and powdered calcium sulfate hemihydrate; when mixed with water, the hemihydrate is chemically converted to calcium sulfate dihydrate and acts as a binder for the Bioglass particles. The calcium sulfate in the PerioGlas Plus and CAPSET devices is absorbed between four and eight weeks after implantation, depending on the graft site, size and material used. The particulate Bioglass in the PerioGlas Plus device is identical to that in the PerioGlas predicate, being substantially absorbed within the six-month timeframe normally associated with bone remodeling. For all three devices, bone forms throughout the graft site with the material being absorbed and replaced by new bone tissue.

In vitro data on the dissolution properties of the device calcium sulfate binder are presented. Characterization data on the residual particulate after dissolution of the calcium sulfate binder also is provided. Prior *in vivo* performance data for the device components are summarized.

7. Warnings and Precautions

PerioGlas Plus does not possess sufficient mechanical strength to support load bearing defects prior to tissue ingrowth. In cases where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

PerioGlas Plus is intended for use by clinicians familiar with bone grafting and internal/external fixation techniques. PerioGlas Plus must not be used to gain screw purchase or to stabilize screw placement.

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8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery. Complications specific to oral/dental use are those as may be typically observed for similar bone grafting procedures and may include: tooth sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, abscess formation

9. Conclusion

PerioGlas Plus is claimed to be substantially equivalent to PerioGlas and CAPSET as a non-structural osteoconductive bone void filler for oral and craniofacial osseous defects. Additional supporting *in vitro* data were supplied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Mr. David M. Gaisser
Director, Operations
NovaBone Products, LLC
One Progress Boulevard, #33
Alachua, Florida 32615

Re: K031073
Trade/Device Name: PerioGlas® Plus-Settable Bone Graft Substitute
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LYC
Dated: August 12, 2003
Received: August 13, 2003

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K031073

Device Name: PerioGlas® Plus - Settable Bone Graft Substitute

Indications For Use:

PerioGlas Plus – Settable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. PerioGlas Plus is indicated to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral and maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); craniofacial augmentation; sinus lifts; cystic defects. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR (Per 21 CFR 801.109) Over-The-Counter Use____